Original Article

Clinical and Radiographic Evaluation of Glass Ionomer Compared to Resin Composite in Restoring Primary Molars: A 1-year Prospective Randomized Study

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Abstract

To compare the clinical performance of glass ionomer (GI) versus resin composite. A total of 40 Class II restorations were placed in 12 patients aged 4–8-year-old. Patients had to have one or more pair of contralateral teeth indicated for Class II restorations. The two materials, GI (ChemFil™ Rock) and resin composite (Z350) were randomly placed in a split mouth design. The restorations were evaluated using foreign direct investment criteria after 3, 6, 9, and 12 months. Data were subjected to statistical analysis. The result did not reflect any significant differences at the first 6 months evaluation. However, change appeared at 9 and 12 months evaluation regarding; anatomic form, fracture of material and retention, marginal adaptation, wear, proximal anatomical form, contact point, proximal contour, radiographic examination, recurrence of caries and periodontal response. Resin composite Z350 showed better clinical performance than ChemFil™ Rock after 1-year follow-up.

Keywords: *Clinical trial, dental restoration, glass ionomer cement, primary teeth, resin composite*

Introduction

Despite the evolution of dentistry in the field of oral health for children, tooth decay remains the most common childhood disease.[1,2] Dental amalgam has been used for treating children's teeth decay and has reflected excellent results. However, its use has been decreasing dramatically as a result of increased esthetic demand and patients' concerns regarding mercury toxicity.[3] Consequently, other esthetic restorative materials used to restore primary teeth have grown exponentially in the past years. The esthetic restoration of caries in primary teeth has always been a challenge for the pediatric dentist. This is due to various reasons, but the most important challenge remains in the inability of children to cooperate, moisture contamination, and the lack of suitable material for this age group.[4]

Resin composite material has become an alternative to amalgam due to its high esthetic property, minimal cavity preparation, and its clinical reliability. In fact, several factors alter its clinical performance and longevity; including its technique-sensitivity, polymerization shrinkage, and high coefficient of thermal shrinkage.[5,6] Around the same period, the glass ionomer (GI) material was introduced with a number of advantages such as high biocompatibility, ability to form chemical bond with dentine and enamel, being fluoride-releasing material, making them anti-cariogenic, and their coefficient of thermal expansion is similar to dentin.[7,8] However, at that stage, GI was difficult to handle and was characterized with poor wear resistance.[1,7] To overcome these inadequacies, other modified GI were developed, for example resin modified GI, polyacid-modified resin-based composites, and metal reinforced GI, which were suitable alternative restorative material for restoring primary teeth.[8,9] In this regard, several studies have evaluated resin composite in Class II restorations in primary molars and reported that resin composite is a successful restoration method.[10] On the other hand, there are little data about the usage of zinc reinforced glass ionomer cements (GICs) *in vitro*[11-13] and to the best of our knowledge, there are no *in vivo* studies addressing the performance of zinc reinforced GI in primary teeth.

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In view of the available data, this study was conducted to evaluate clinically these two restorative materials.

The null hypothesis is that there will be no differences between the two tested materials during a 1-year follow-up.

Materials and Methods

A total of 46 molars indicated for Class II restorations were selected as a sample size in healthy patients aged between 4- and 8-year-old from Beirut Arab University Diagnostic Center to receive their treatment at the specialty clinic. The sample size was determined using www.raosoft.com with an expected attrition rate of 15% at a 95% confidence level. The current study was conducted after receiving the approval from the Ethical Committee and Institutional Review Board code (2015H-017-D-M-0051). The patients' guardians were informed of the study purposes, procedures and a written informed consent was signed by all patients' guardians.

The teeth selected for inclusion in the study were required to meet the following criteria bilateral and contralateral primary molars indicated for Class II restorations with no history of spontaneous pain, no tenderness to palpitation or percussion, free of abscess or fistula, no abnormal mobility, radiographic evidence of an intact lamina dura, no radiographic evidence of internal root resorption or inter-radicular or periapical pathosis and not expected to exfoliate within at least 2 years. During 1 month, all restorations were placed by one operator. A bitewing radiograph was taken for each molar during the selection procedure [Figure 1].

Local anesthesia was administered, an appropriate rubber dam isolation was applied during all the procedure, access to Class II cavities was made using high-speed water-cooled Carbide Burs No. 330 approximately with the depth of 0.5 mm in dentine and width of one-third of the occlusal table, and the cavo-surface margins were not beveled. Later caries removal was completed with low-speed rose-head burs. After finishing the cavity, a matrix (Palodent®, Germany) was placed with an interproximal plastic wedge (DENTSPLY, Germany) [Figure 2].

In a split mouth design, the prepared primary molars were randomly assigned as per the restorative material used which was either ChemFil™ Rock or resin composite using a flip of coin maintaining a single blindness method. The materials were placed and finished as per the manufacturer recommendations.

In the first group, twenty primary molars were cleaned through water rinsing with oil free air for 10 s to avoid dentin desiccation. The capsule of zinc ChemFil™ Rock was activated by depressing the plunger. Then, it was immediately placed in the activator (Kerr, USA) to be mixed for 15 s after which the capsule was instantly removed from the capsule activator and placed into the capsule extruder (DENTSPLY, Germany) to be applied in the prepared cavity. Finally, it was adapted with the plastic filling instrument, and after 6 min from activation, it was finished with (Enhance™ Finishing System, DENTSPLY, Germany).

In the second Group, the twenty primary molars were etched with 32% phosphoric acid for 15 seconds (3M ESPE, St. Paul, MN, USA), then rinsed to remove any residual acid for 15 s and dried with oil-free air for 10 s to leave the cavity moist to avoid dentine desiccation. Subsequently, the bond Adper™ Single Bond 2 Adhesive (3M ESPE, St. Paul, MN, USA), was applied in two sequential coats, dried gently for 5 s and cured for 10 s, resin composite was applied in 2 mm increments and cured for 20 s [Figure 3]. After application of the restorative material, the rubber dam was removed, the occlusion was checked and adjusted using articulating paper. The restoration was finished at the same visit using standardized procedures starting from the course, medium and then fine diamond abrasive burs. Finally, the restoration was accomplished with polishing burs.

Follow-up visits were after 3, 6, 9, and 12 months [Figures 4-8]. The restorations were assessed independently

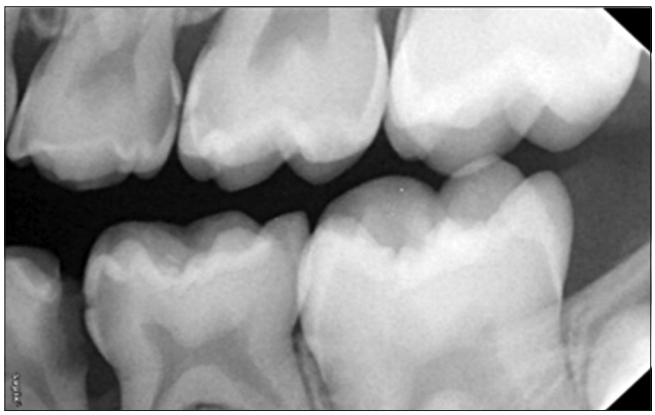

Figure 1: Bitewing radiograph with proximal caries in second primary molars

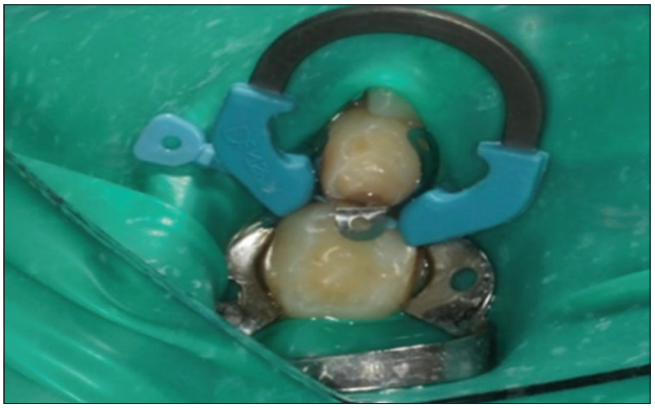

Figure 2: Rubber dam isolating lower first primary molars with Interproximal wedge with sectional matrix

using World Dental Federation (FDI) evaluation criteria which include esthetic, functional, and biological properties by three experienced, calibrated evaluators using mirrors, probes, and radiographs. Radiographic assessment was performed only at 6 and 12 months based on the recommendation of the American Academy of Pediatric Dentistry. In addition, the operators used the FDI criteria tool "www.e-calib.info" for training and calibration. The clinical intra-examiner calibration was conducted with Class II, which were re-examined after 20 days. An intra-agreement of at least 95% was gained before initiating the study. This training was repeated before each evaluation to guarantee reproducibility.

For the evaluation purposes of this study, 14 of 16 parameters of the FDI criteria were used; which include Staining (surface and margin), esthetic anatomical form, fracture of material and retention, marginal

Figure 3: Lower 1st primary molar restored with Z350

Figure 4: Preoperative photograph with bilateral proximal caries

Figure 5: At 3 months follow up the right quadrant filled with Z350 and ChemFil™ Rock on the left quaderant

Figure 6: At 6 months follow-up, the right quadrant filled with Z350 and ChemFil™ Rock on the left quaderant

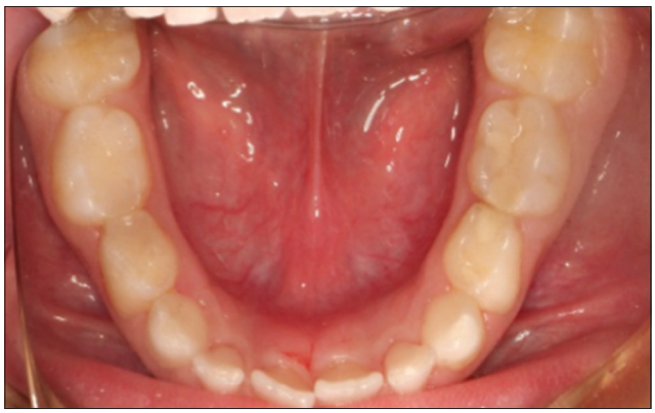

Figure 7: At 9 months follow-up, the right quadrant filled with Z350 and ChemFil™ Rock on the left quaderant

Figure 8: At 12 months follow-up, the right quadrant filled with Z350 and ChemFil™ Rock on the left quaderant

adaptation, wear, proximal anatomical form (contact point and contour), radiographic examination, patient's view, postoperative hyper-sensitivity and tooth vitality, recurrence of caries, tooth integrity (enamel cracks and tooth fractures), periodontal response, adjacent mucosa, oral, and general health. The other two parameters surface luster and color match were not assessed as the resin composite is visually better in both.

Five steps grading method was used to evaluate the 14 selected parameters (1 - clinically excellent/very good, 2 - clinically good, 3 - clinically sufficient/satisfactory, 4 - clinically unsatisfactory, and 5 - clinically poor). When restoration receives a score of 4 or 5, it was recorded as a failure.

After 3, 6, 9 months, and 1 year, the data obtained were statistically analyzed using the SPSS version 13.0 program (SPSS Inc., Chicago,). A Mann–Whitney U-test was performed to identify differences in FDI score between ChemFil™ Rock and resin composite.

Results

All details regarding patient's age, gender, and the distribution of the treated teeth as per number of teeth and the type of restoration is presented in Tables 1 and 2.

Clinically, excellent results were noted for the three main properties of the FDI criteria at 3, 6, 9, and 12 months recall for the resin composite restorations, taking into consideration that one patient with two restorations dropped out at 6 months. The same results were noted at 3 and 6 months recall for ChemFil™ Rock restorations with no statistically significant differences.

At 9 months, 15 ChemFil™ Rock restorations showed clinical excellent results. However, four restorations showed deteriorations, of which two restorations obtained a poor clinical score in anatomic form, proximal anatomical form; contact point, proximal anatomical contour, radiographic examination, and recurrence of caries, in addition to unsatisfactory score in marginal adaptation and fracture of material, and a good clinical score in wear and periodontal response. These two failed restorations were replaced. The other two restorations reflected a good clinical score in anatomical form, marginal adaptation and fracture of material and were followed up.

At 12 months, the two restorations that showed the clinically good score at 9 months showed further deterioration in the anatomic form, fracture of material and retention, marginal adaptation, wear, proximal anatomical form contact point, proximal anatomical contour, radiographic examination, recurrence of caries, and periodontal response. These two failed restorations were also replaced at 12 months.

Statistical analysis revealed that there were significant differences in FDI scores for sub-mentioned criteria at 9 and 12 months at $p = 0.05$ with a confidence level of 95% [Table 3]. For the four failed ChemFil™ Rock restorations, the esthetic property reflected clinically poor restoration, as the esthetic anatomic form was completely unsatisfactory and the proximal contact point was too weak with insufficient contour leading to food impaction. Furthermore, the functional property reflected clinically unsatisfactory restoration, as the presence of bulk fractures with less than half of the restorative material lost and the presence of large irregularities was detected. Finally, the biological property reflected that two of four ChemFil™ Rock restorations were clinically poor due to the presence of deep caries exposing the dentin which required repairing. Meanwhile, the periodontal response was clinically good as it showed little plaque.

Discussion

Nowadays, a lot of researches are being conducted to identify the ideal esthetic restorative material to be used in restoring carious primary teeth. Consequently, resin composite has been continuously improved over the past years as it is a highly esthetic material yet it is still a technique sensitive material that requires efficient moisture control and high standard of patient cooperation in this perspective GIs was introduced.[8,14] Several attempts were

Table 1: Children distribution according to child's age and gender

Gender	*n*					Percentage				
	5 years old	6 years old	7 years old	8 years old	Total	5 years old	6 years old	7 years old	8 years old	Total
Male	0	3	0	3	6	0	50.0	0	50.0	100
Female	1	2	2	1	6	16.7	33.3	33.3	16.7	100
All children	1	5	2	4	12	8.3	41.7	16.7	33.3	100

Table 2: Restorations distribution according to tooth type and restoring material

Restoring material	*n*			Percentage		
	First deciduous molar	Second deciduous molar	Total	First deciduous molar	Second deciduous molar	Total
ChemFil™ Rock	4	16	20	20.0	80.0	100
Resin composite	4	16	20	20.0	80.0	100
All restorations	8	32	40	20.0	80.0	100

conducted to enhance the mechanical and esthetic properties of GI restorations as it is characterized by its simple manipulation, biocompatibility, and fluoride releasing property. Therefore, this study was carried out to compare the clinical performance of two recently introduced brands of these two materials.

Anatomically, the primary teeth have broad flat contact which leads to food impaction at the smooth surface and increases the incidence of the proximal cavity.[15] Therefore, this study evaluated the clinical performance of resin composite in Class II, since, it was shown to be an effective restoration for permanent teeth.[16] However, a few documented clinical trials have been conducted on primary teeth. In addition, no clinical studies were executed to evaluate ChemFil™ Rock as a proximal restoration in primary teeth.[11-13]

The randomized clinical trial was used as it is considered the best study design.[16] In addition, the split-mouth design was chosen to expose the two restorative materials to nearly identical oral environmental conditions and to eliminate any bias due to patient variables.[17] Moreover, all restorations were placed with rubber dam to maintain a dry field and standardization; even though, it is not required for GI as recommended by the manufacturer. A separation ring was used with a sectional matrix for teeth that have contact with the adjacent, as studies showed it produced tight

Table 3: Mann-Whitney U-test results to assess the significant differences between ChemFil™ Rock group and resin composite group according to studied period and studied criterion

Studied criterion	Criterion categories	ChemFil Rock™	Success rate (%)	Resin composite	Success rate (%)	*P*	Significant difference?
	Studied period (after 3 months)						
Esthetics properties	Surface staining	20	100	20	100	1.000	No
	Marginal staining	20	100	20	100	1.000	No
	Anatomic form	20	100	20	100	1.000	No
Functional properties	Fracture of material and retention	20	100	20	100	1.000	No
	Marginal adaptation	20	100	20	100	1.000	No
	Wear	20	100	20	100	1.000	No
	Proximal anatomical form						
	Contact point	20	100	20	100	1.000	No
	Contour	20	100	20	100	1.000	No
	Radiographic Examination	20	100	20	100	1.000	No
	Patient's view	20	100	20	100	1.000	No
Biological properties	Postoperative (hyper) sensitivity and tooth vitality	20	100	20	100	1.000	No
	Recurrence of caries	20	100	20	100	1.000	No
	Tooth integrity	20	100	20	100	1.000	No
	Periodontal response	20	100	20	100	1.000	No
	Adjacent mucosa	20	100	20	100	1.000	No
	Oral and general health	20	100	20	100	1.000	No
	Studied period (after 6 months)						
Esthetics properties	Surface staining	19	100	19	100	1.000	No
	Marginal staining	19	100	19	100	1.000	No
	Anatomic form	19	100	19	100	1.000	No
Functional Properties	Fracture of material and retention	19	100	19	100	1.000	No
	Marginal adaptation	19	100	19	100	1.000	No
	Wear	19	100	19	100	1.000	No
	Proximal anatomical form						
	Contact point	19	100	19	100	1.000	No
	Contour	19	100	19	100	1.000	No
	Radiographic examination	19	100	19	100	1.000	No
	Patient's view	19	100	19	100	1.000	No
Biological properties	Postoperative (hyper) sensitivity and tooth vitality	19	100	19	100	1.000	No
	Recurrence of caries	19	100	19	100	1.000	No
	Tooth integrity	19	100	19	100	1.000	No
	Periodontal response	19	100	19	100	1.000	No
	Adjacent mucosa	19	100	19	100	1.000	No
	Oral and general health	19	100	19	100	1.000	No

Contd...

Table 3: Contd...

Studied criterion	Criterion categories	ChemFil Rock™	Success rate (%)	Resin composite	Success rate (%)	*P*	Significant difference?
Studied period (after 9 months)							
Esthetics properties	Surface staining	19	100	19	100	1.000	No
	Marginal staining	19	100	19	100	1.000	No
	Anatomic form	19	89.5	19	100	0.037	Yes
Functional properties	Fracture of material and retention	19	78.9	19	100	0.037	Yes
	Marginal adaptation	19	78.9	19	100	0.037	Yes
	Wear	19	100	19	100	0.152	No
	Proximal anatomical form						
	Contact point	19	89.5	19	100	0.152	Yes
	Contour	19	89.5	19	100	0.152	Yes
	Radiographic examination	19	89.5	19	100	0.152	Yes
	Patient's view	19	100	19	100	1.000	No
Biological properties	Postoperative (hyper) sensitivity and tooth vitality	19	100	19	100	1.000	No
	Recurrence of caries	19	89.5	19	100	0.152	Yes
	Tooth integrity	19	100	19	100	1.000	No
	Periodontal response	19	100	19	100	0.152	No
	Adjacent mucosa	19	100	19	100	1.000	No
	Oral and general health	19	100	19	100	1.000	No
Studied period (after 12 months)							
Esthetics properties	Surface staining	19	100	19	100	1.000	No
	Marginal staining	19	100	19	100	0.317	No
	Anatomic form	19	78.9	19	100	0.037	Yes
Functional properties	Fracture of material and retention	19	78.9	19	100	0.037	Yes
	Marginal adaptation	19	78.9	19	100	0.037	Yes
	Wear	19	100	19	100	0.037	No
	Proximal anatomical form						
	Contact point	19	78.9	19	100	0.037	Yes
	Contour	19	78.9	19	100	0.037	Yes
	Radiographic examination	19	78.9	19	100	0.037	Yes
	Patient's view	19	100	19	100	1.000	No
Biological properties	Postoperative (hyper) sensitivity and tooth vitality	19	100	19	100	1.000	No
	Recurrence of caries	19	78.9	19	100	0.037	Yes
	Tooth integrity	19	100	19	100	1.000	No
	Periodontal response	19	100	19	100	0.037	Yes
	Adjacent mucosa	19	100	19	100	1.000	No
	Oral and general health	19	100	19	100	1.000	No

proximal contact.[18] Although clinical evaluation was done after 3, 6, 9, and 12 months, radiographic assessment was done only at 6 and 12 months based on the recommendation of the American Academy of Pediatric Dentistry, to avoid excessive radiation exposure.

The restorations were evaluated for restoring functional, biological form and esthetic properties using FDI criteria as it is more sensitive to small variations in the clinical outcomes compared to the modified USPHS criteria.[19] Thus, recent studies are using the FDI criteria.[20,21]

The results of this study revealed clinically excellent/very good for both restorative materials for the three main properties of the FDI criteria up to 6 months. These satisfactory results came in accordance with other studies. Pascon *et al*. evaluated the clinical performance of microfilled resin composite versus two types of polyacid-modified GI in Class II primary teeth.[21] dos Santos, Passos, and Maia, also evaluated 13 resin-modified GI, 15 polyacid modified GI and 16 resin composite in Class II restoration for primary molars,[22] both studies reflected satisfactory results when comparing resin composite with other type of GI up to 6 months.

Moreover, up to 12 months, resin composite had superior clinical performance, all restorations demonstrated clinically excellent outcome up to 1 year despite its limitation in pediatric dentistry as being more technique sensitive, requires efficient moisture control and patient cooperation.[5,15] Dos Santos Pinto *et al*. used a different

study design to evaluate the survival of resin composite, resin modified GI and conventional GI up to 4 years retrospectively and found that the resin composite presented a better survival rate than both types of GIC this was attributed to the materials' mechanical properties.[23]

Resin composite superior performance was also pointed out by Sengul, F., and Gurbuz, T. when they assessed the survival rates of resin modified GI, compomer, giomer, and hybrid resin composite for 2 years using the FDI criteria. They determined the success rate of Hybrid composite resin (95%), Resin modified GIC (91%), giomer composite resin (89%), and compomer (86%). This superior performance was noted due to the filler content which enhanced the physical properties of resin composite, in addition, to the light curing property which provided the immediate material setting.[9]

GI restoration was introduced as more convenient material in pediatric dentistry, and numerous efforts have been exerted to evaluate the effectiveness of the GI restoration material. In this study, ChemFil™ Rock showed clinically excellent performance at 6 months for all assessed parameters. At 9 months, it showed 87% success rate for the following parameters; anatomic Form, proximal anatomical form, wear, recurrence of caries, and radiographic examination, whereas fracture of material and marginal adaptation showed 78.9% success rate. Furthermore, at 12 months, the success rate declined to 78.9% for the same identified parameters at 9 months, except for marginal staining and periodontal response success rate which was 94.7%.

The failure in ChemFil™ Rock restorations was noticed in four restorations. These restorations lost their form at the proximal surface which was caused by material fracture at the cavity isthmus that could be avoided by more roundation of the axiopulpal line angle to reduce the concentration of stress and to provide the greater bulk of restorative material in this area.[15] This can be also attributed to the fact that the ChemFil™ Rock has the lower mechanical strength and lower fracture toughness.[12] It is worth mentioning that, the teeth did not lose its vitality nor have any endodontic complication even though there was secondary caries, this might be explained by fluoride releasing effect, further long-term studies are required to better visualize the cariostatic effect of ChemFil™ Rock.

Although the four failed ChemFil™ restorations lost their form at the proximal surface, the occlusal surface the restoration was intact. The same results were also noted by dos Santos, Passos, and Maia when they assessed the resin-modified GI, polyacid modified GI and resin composite in Class I and II restoration primary molars, they found that the survival rate of Class I restorations were higher than Class II for both restorative material this was attributed to the deeper and bigger cavity size of Class II restorations which reduced the bond strength to dentin and increased the exposure of the material to occlusal forces.[22] Similar results were found by Dos Santos Pinto *et al.* who evaluated retrospectively the survival rate of resin composite, resin modified GI and conventional GI up to 4 years.[23]

This study has the following limitations:

1. The wear criterion was not measured quantitatively using 3D laser scanning
2. Inability to measure the exact amount of lost restoration as the study was done clinically
3. One year is a relatively short period to evaluate the long term dental adhesive materials
4. The bitewing radiograph was not standardized because of the patients' young age and inability to cooperate.

Conclusion

Despite the study limitations, it can be concluded that resin composite restorative materials performed satisfactorily over 1 year. Moreover, ChemFil™ Rock restorations is an acceptable material that can be used in non-load bearing areas in primary teeth as the clinical failure that occurred in ChemFil™ Rock was noted in the proximal part of the filling.

1. Further investigations with larger sample size and longer follow-up period would be indicated for better performance assessment of such restorations in the long-term
2. In addition, an *in vitro* study should be conducted after teeth shedding to give more details
3. ChemFil™ Rock could be recommended for Class I restorations, for ART or IRT due to its anticariogonicity and friendly technique of application which makes it suitable for uncooperative patients.

Importance of this study for pediatric patients

- To evaluate which material-resin composite or Zinc reinforced GI will provide better clinical performance for pediatric patients in its esthetic, functional, and biological properties
- To help pediatric dentists choose a better restorative material for Class II cavities in primary molars.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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